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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,458	02/07/2002	John N. Feder	D0114 NP	9950

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,458	FEDER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8-9, and 16-19, drawn to an isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95.0% identical to a polynucleotide fragment of SEQ ID NO: 1, a recombinant vector and host cell, and a method of making a polypeptide, classified in class 536, subclass 23.1.

II. Claims 5-6, 10, and 20, drawn to an isolated polypeptide comprising an amino acid sequence at least 91.0% identical to a polypeptide fragment of SEQ ID NO: 1, classified in class 530, subclass 350.

III. Claim 7, drawn to an isolated antibody that specifically binds to the isolated polypeptide, classified in class 530, subclass 387.1.

IV. Claims 11 and 21-33, drawn to a method for preventing, treating, or ameliorating a medical condition comprising the step of administering a therapeutically effective amount of a polypeptide, classified in class 514, subclass 12.

V. Claims 11 and 21-33, drawn to a method for preventing, treating, or ameliorating a medical condition comprising the step of administering a therapeutically effective amount of a polynucleotide, classified in class 514, subclass 44.

VI. Claim 12, drawn to a method of diagnosing a pathological condition comprising determining the presence or absence of a mutation in the polynucleotide, classified in class 435, subclass 6.

VII. Claim 13, drawn to a method of diagnosing a pathological condition comprising determining the presence or amount of expression of the polypeptide in a biological sample, classified in class 435, subclass 7.1.

VIII. Claim 14, drawn to a process for making polynucleotide sequences encoding a gene product having altered potassium channel beta subunit activity, classified in class 435, subclass 4.

IX. Claim 15, drawn to a shuffled polynucleotide sequence, classified in class 536, subclass 44.

X. Claim 34, drawn to a method of proliferating hematopoietic stem cells comprising the step of administering to a mammalian subject an antagonist of the polypeptide, classified in classification dependent upon structure of antagonist.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-III and IX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used other than to make the protein of Group II, such as in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The polynucleotide of Group IX is functionally and structurally different than the products of Groups I, II, and III and can be used in methods other than those Groups I, II, and III, such as generating transgenic/knockout mice.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions IV-VIII and X are different methods because they require different ingredients, process steps, and endpoints. Groups IV-VIII and X are different methods requiring different method steps, wherein each is not required, one for another.

For example, Group IV requires the search and consideration of efficacy of treatment of administering a polypeptide, which is not required by the other inventions. Group V requires search and consideration of efficacy of therapy of administering a polynucleotide, which is not required by the other inventions. Group VI requires search and consideration of diagnosing a pathological condition or susceptibility to a pathological condition by determining the presence or absence of a mutation in a polynucleotide sequence, which is not required by the other inventions. Group VII requires search and consideration of diagnosing a pathological condition or susceptibility to a pathological condition by determining the presence or amount or expression of a polypeptide, which is not required by the other inventions. Group VIII requires search and consideration of making shuffled polynucleotide sequences that encode a gene product having altered potassium channel beta subunit activity, which is not required by the other inventions. Group X requires search and consideration of efficacy of therapy of administering a polypeptide antagonist to a mammalian subject to proliferate hematopoietic stem cells, which is not required by the other inventions.

c. Inventions I and V/VI/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as DNA purification or generating transgenic mice.

d. Inventions II and IV/VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as immunoassays or as an antigen for the production of antibodies.

e. Inventions I and IV/VII/X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and IV/VII/X are unrelated product and methods, wherein each is not required, one for another. For example, the nucleic acid molecule of Invention I cannot be used together with the claimed methods of Inventions IV/VII/X because these inventions do not recite the use or production of the nucleic acid molecule of Invention I.

f. Inventions II and are V/VI/VIII/X unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups II and V/VI/VIII/X are unrelated product and methods, wherein each is not required, one for another. For example, the polypeptide of Invention II cannot be used together with the claimed methods of Inventions V/VI/VIII/X because these inventions do not recite the use or production of the polypeptide of Invention II.

g. Inventions III/IX and IV-VIII/X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups III/IX and IV-VIII/X are unrelated products and methods, wherein each is not required, one for another. For example, the antibody of Invention III and the shuffled polynucleotide of Invention IX cannot be used together with the claimed

methods of Inventions IV-VIII/X because these inventions do not recite the use or production of the antibody of Invention III or the shuffled polynucleotide of Invention IX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirements, different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
April 21, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER